

### **REMARKS**

Claims 35, 37-40 and 42-51 are pending following entry of the present amendment. Claims 1-34, 36, and 52-57 are cancelled. By this amendment, the limitations of former claims 36 are incorporated into claim 35, which now recites that the hyperlipidemia to be treated is associated with LPL or ApoE deficiency.

#### **Rejections Under 35 U.S.C. § 112**

Claims 46 and 50 are rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness of the phrase “hybridizes under stringent conditions”. While Applicants respectfully submit that the metes and bounds of the term stringent hybridization conditions are well understood in the art, this allegedly objectionable term has been omitted from the claims as amended herein, thereby obviating this asserted ground for rejection.

Claims 35-40, 42-45, 47-50 and 51 are rejected under 35 U.S.C. § 112, first paragraph based on the assertion that the specification, while being enabling for a method of treating hyperlipidemia associated with LPL or ApoE deficiency, comprising the administration of an adenoviral vector containing the coding sequence for an LPL S447X protein, does not reasonably provide enablement for the treatment of any other conditions. The claims as amended are limited to the treatment of hyperlipidemia associated with LPL or ApoE deficiency, using a viral gene therapy vector. Dependent claims are limited to adenoviral or AAV vectors.

The foregoing amendments are presented without prejudice or accession to the merits of the grounds for rejection asserted by the Office, and Applicants reserve the right to prosecute all subject matter withdrawn from the claims by these amendments in a related US application.

It is respectfully submitted that the claims as amended are fully enabled by the specification.

#### **Double Patenting and Rejections Under 35 U.S.C. § 103**

In the Action mailed on 26 October, 2006, claims 35, 36, 38, 39, 42-44, 47, 48, and 51 were rejected under the judicially created doctrine of obviousness-type double patenting over Patent No. 6,814,962, and under 35 U.S.C. §103 over WO 96/11276, in view of Kozaki et al as

evidenced by Gotada et al.

The Examiner asserts that the ability of LPL S447X to lower triglycerides and to raise HDL-C is an inherent property of the protein. With respect, it is submitted that there is no such inherent property of that protein. Rather, that surprising therapeutic benefit may be achieved only if that protein is administered **in an amount that is effective to achieve that result**. It is submitted that there is nothing in the art that suggests that viral gene therapy vectors could be used to administer an amount of protein that would be effective in this way, much less any basis for a reasonable expectation that viral vectors could be used to deliver an amount of S447X therapeutic that would have this effect.

#### Sequence Compliance

With respect to the Sequence Listing filed on 02/08/2006 the computer readable form and paper copy of the Sequence Listing are the same and present no new matter. A formal statement to this effect will be filed under separate cover.

#### Conclusion

The applicants submit that the claims are in condition for allowance and respectfully request that a timely Notice of Allowance be issued in this case.

Date: December 18, 2007

Respectfully Submitted,

**BLACK LOWE & GRAHAM PLLC**

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